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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,407	04/22/2005	Adel Penhasi	030231-0158	9132

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,407	PENHASI ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 102* is/are pending in the application.

4a) Of the above claim(s) *1 - 88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89 - 102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 12, 2009 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 89, 91, and 93 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 45 and 47 – 49 of copending Application No. 10/555310 in view of US Patent 5,840,332. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 20, 2009 and those set forth herein.

Applicant does not argue the merits of the rejection and requests the removal of this rejection following reconsideration and withdrawal of the other rejections.

As other rejections remain, this provisional rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112 – 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 89 – 102 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This written description rejection is MAINTAINED for the reasons of record set forth set forth in the Office Action mailed February 20, 2009 and those set forth below.

Applicants traverse this rejection on the grounds that the delayed burst release formulations encompasses a genus wherein the species are represented by the choice of each component of the core containing venlafaxine, at least one burst control agent and disintegrant and an outer coating containing a water insoluble hydrophobic carrier and a water insoluble but hydrophilic particulate matter. The specification clearly describes the materials that can be used for the various components of the core and coating. By choosing an appropriate compound, one of ordinary skill can readily practice and use the claimed invention.

These arguments are unpersuasive. Exemplary substances for the various components of the formulation are given in the specification. However, the claims do not merely recite the composition with the core and outer coating as described by Applicant but also include functional limitation such as that the formulation releases substantially

no venlafaxine *in vitro* for two hours. The data present in the specification does not provide adequate guidance as to which of the formulations described in the specification also possess this functional limitation. The release profile of the active ingredient will depend on which components are selected and the amounts of the various ingredients present in the composition. Adequate data as to how the release profile is affected by the components selected and/or the amounts of those components that give rise to the required release profile are not given in the specification. No data for a variety of formulations and/or formulations with varying amounts of the various ingredients and the release profile of these varied formulations is present, so one skilled in the art cannot ascertain how the disclosed structure relates to the functional limitation present in the claims. Therefore, the full scope of compositions with the requisite structure and functional limitations do not meet the written description provision.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 89 – 102 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the phrase "substantially no" was not defined by the specification. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 20, 2009 and those set forth below.

Applicants traverse this rejection on the grounds that the person of ordinary skill would be readily understood to mean that "a considerable amount of venlafaxine would not be release…for two hours." The terms must be given their plain meaning.

This argument is unpersuasive. The Examiner concurs that a plain meaning of substantially no would be that a considerable (or substantial) amount of venlafaxine is not released but this does not define what level of release would or would not meet the claim limitation. Just as with "substantially no", "a considerable amount" is a relative term that has not been defined. Depending on the circumstances, a "considerable amount" could be just a few percent or much higher amounts. As Applicants have not provided any guidance on amounts that are considered to be either insubstantial or considerable, this rejection is maintained.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 89 – 99 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (US 6,274,171) in view of Lerner et al. (US 5,840,332). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 20, 2009 and those set forth below.

Applicants traverse this rejection on the grounds that neither reference teaches a substantially even blood plasma concentration of venlafaxine as a property displayed by the formulation. Even if one were to accept the assertion by the Examiner that the limitations regarding venlafaxine must inherently be met as both the instant claims and the cited prior art teach the same formulation, the prior art formulation does not display the same advantageous physiological properties as the formulations recited in the instant claims. It is not sufficient to establish inherency that a certain thing may be true.

The extended release tablets of Sherman results in substantially variation in blood plasma levels of the first four hours following administration. The gastrointestinal delivery system of Lerner fails to resolve the deficiency of Sherman. Claims 91 and 93 have different preambles but both recite the same formulation as claim 89.

These arguments are unpersuasive. "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." **MPEP 2113** Applicants have not presented any evidence that the compositions of the cited prior do not meet the functional limitation set forth in the claims and that the instant formulations display advantageous physiological properties. Arguments without factual support are mere allegations and are not found to be persuasive.

The venlafaxine tablets disclosed by Sherman comprise a core of venlafaxine hydrochloride; a filler such as microcrystalline cellulose, which reads on a burst control agent, and water soluble cellulosic polymer such as HPMC (col 2, ln 63 – col 3, ln 2), which reads on the disintegrant of the instants claims. This core is coated with a water insoluble hydrophobic carrier but no water-insoluble, hydrophilic particulate material is present. This deficiency is remedied by Lerner et al. which discloses that such particles in a water insoluble hydrophobic carrier results ni the formation of channels that for drug release. Therefore the compositions of the cited prior art meet the structural limitations of the instant claims. The same composition with the same structure must have the same properties. The same compositions cannot have mutually exclusive properties. This is not something that is only true some of the time. These compositions are then

administered orally to patients to bring about the therapeutic effect of the active ingredient venlafaxine. The active step of instant claims 89, 91 and 93 is the oral administration of such a formulation. When the same composition is administered, the same effects must ensue, whether it be diminished side effects or improved patient compliance. As the same composition is administered orally in the cited prior art as in the instant claims, the same effects must ensue. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). In this case, the unappreciated property that occurs upon administration is decreased side effects and/or improved patient compliance.

If there are features that differ between the cited prior art and the formulations of the instant claims that possess the requisite release profile (e.g., specific ingredients or amounts of the various components), such features should be present in the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "substantially even blood plasma concentration") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Claims 89 – 102 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. and Lerner et al. further in view of Upton et al. (US 5,506,270). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 20, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Upton is cited as teaching a venlafaxine dose between 25 mg/day and 200 mg/day and the Examiner opines as reads on the 60 mg dose in claim 99 – 102. The deficiencies of Sherman et al. and Lerner et al. were discussed above and Upton does not remedy these deficiencies. The data of table 3 of Sherman et al. shows substantial variation in the blood plasma level that decreases substantially over a 24 hour period. This data would surely not prompt a physician or formulation chemist to use a lower dose as recited in the instant claims. The Examiner uses impermissible hind-sight.

These arguments are unpersuasive. As discussed above, Sherman et al. and Lerner et al. are not deficient when it comes to the appreciation of the properties recited in the preamble of the instant claims. Thus, Upton et al. is not required to cure this deficiency.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The Examiner set forth criteria that one of ordinary skill in the art would use to optimize the dosage of the active ingredient within the range disclosed by Upton such as the dosing frequency, the condition being treated, the weight of the patient and the severity of the condition (see p 11 of the February 20, 2009 Office Action). Applicants have not persuasively argued why one of ordinary skill would not select a dosage of 60 mg, given the range of 25 mg/day and 200 mg/day taught in the cited prior art. As to the decrease in venlafaxine levels displayed in table 3, neither Applicants nor any of the cited references indicate the therapeutic window of the drug and the levels at the end of the profile may be above the minimum effective concentration required to bring about a therapeutic effect. Thus a decrease over time does not necessarily indicate that the dosage form does not provide a therapeutic blood plasma level of venlafaxine for an entire 24 hour period.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW